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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,868	12/03/2004	Dorothy French	P1959R1	1564

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GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER
HIRIYANNA, KELAGINAMANE T

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
01/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,868	FRENCH ET AL.	
	Examiner	Art Unit	
	Kelaginamane T. Hiriyanna	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,11,179,181,182 and 187-196* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-11, 179, 181-182 and 187-196* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/06/2007 has been entered.

Applicant's response filed on 11/06/2007 in response to office action mailed on 06/14/2007 has been acknowledged.

Claims 1-9, 12-178, 180, and 183-186 are cancelled.

Claims 10-11 and 189 are amended.

Claims 10-11, 179, 181-182 and 187-196 are pending and are examined in this office action.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Claim Rejections - 35 USC § 112 (1st paragraph)

Claims 10, 11, 189 and their dependent claims 179, 181-182, 187-188 and 190-196 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a FGF19 transgenic mouse wherein transgene is expressed under the control of a MLC promoter and wherein said transgenic mouse has a phenotype of developing hepatocellular carcinoma (HCC), is not enabled for a HCC mouse wherein

the FGF19 gene is driven by any promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of instant invention encompasses obtaining a transgenic mouse with a phenotype of hepatocellular carcinoma (HCC) by expressing FGF-19 transgene under the control of any promoter (gene promoter). However, the specification only provides guidance and/or evidences regarding generation of a transgenic mouse with FGF19 cDNA driven by MLC promoter and its characterization (Example 8, p.91-95) and a method of drug screening (p.96, 3rd paragraph bridging p.97-98). The application does not disclose any other transgenic animals/mice with hepatocellular carcinoma phenotype wherein a FGF19 transgene was expressed under a different promoter other than the single example of said MLC promoter. Since the specification fails to disclose other broadly claimed gene promoters that were used for driving FGF19 transgene expression in deriving a mouse with hepatocellular carcinoma, it is unclear how one skilled in the art could use the invention as claimed given the unpredictability in the art regarding using any promoter in generating cancer. Apart from the art established fact regarding the tissue specificity and species specificity of many of the gene promoters, it has also been observed that a promoter expressing the same gene may cause cancer in one species tissue may not do so in other species. For example Roberts et al (2000, Toxicology Letters 112:49-57) observes that there is a clear species difference in hepato-carcinogenic sensitivity attributed to peroxisome proliferators (PPs) in rodents, guinea pigs and humans that is mediated by acyl CoA oxidase (ACO). Roberts (supra) indicates that this species difference could be attributed to qualitative differences in the response of the gene promoters. Human ACO gene promoter differs in sequence and activity from the rat equivalent (Abstract; p.56, col.1). Thus applicant's disclosure does not enable one skilled in the art to practice the invention as claimed without further undue amount of experimentation, which requires the identification and characterization of sufficient number of examples of gene promoters for their ability to induce hepatocarcinogenesis in a mouse having a FGF19 gene expressed under their control. At issue, under the enablement requirement of 35 U.S.C. 1 12, first paragraph is whether, given the Wands-

factors, the experimentation was undue or unreasonable under the circumstances. "Experimentation must not require ingenuity beyond that to be expected of one of ordinary skill in the art." See Fields v. Conover, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970).

Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Kelaginamane Hiriyanna Ph.D., whose telephone number is (571) 272-3307. The examiner can normally be reached Monday through Friday from 9 AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach Ph.D., may be reached at (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

Kelaginamane T. Hiriyanna
Patent Examiner
Art Unit 1633

AU 1633